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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MINNIFIELD, NITA M	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/774,602	**Applicant(s)** DRUILHE, PIERRE	
	Examiner N. M. Minnifield	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *25 August 2005*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112, 2nd rejection of claims 28 and 29.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *28*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *3-9,25-27 and 29*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: PLEASE SEE ATTACHED.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

N. M. Minnifield
Primary Examiner
Art Unit: 1645

ADVISORY ACTION

1. Applicant's after amendment filed June 27, 2005 is acknowledged and has been entered. Claims 1, 2 and 10-24 have been canceled. Claims 7 and 27-29 have been amended. Claims 3-9 and 25-29 are now pending in the present application. All rejections have been withdrawn in view of Applicant's amendment to the claims and/or comments, with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 4, 9, 25-27 and 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a vaccine composition against malaria comprising a peptide comprising epitopes contained in a MSP-3b peptide (SEQ ID NO: 12), a MSP-3c peptide (SEQ ID NO: 13) or a MSP-3d peptide (SEQ ID NO: 14) or combinations of these peptides and a pharmaceutically acceptable carrier.

Example 6 of the specification (pp. 32-35) sets forth Clinical Studies using MSP-3 with an adjuvant formulation. Example 7 of the specification sets forth Safety Data with immunization of MSP-3 (pp. 35-37). Example 9 of the specification sets forth Immunological Data at page39 and Example 10 discloses data on the antibody responses at page 40 of the specification. Example 11 of the specification teaches Functional Bioassays (p. 42). "The Long Synthetic Peptide

formulation of MSP-3 proved safe: adverse reactions were infrequent, when they occurred they were only localized and not generalized, they were self-resolving, of short duration -generally disappearing within 24 hours-, they did not induce pain and did not led the volunteers to consult: those side-effects, when they existed, were seen only on normal visits. These results are better in terms of safety than those recorded previously using either MSP-1 1.19 in alum or MSP-1 and MSP-2 combinations with Montanide, where severe contro-lateral effects on the previous injection sites, and generalized reactions with fever were recorded. Therefore, the LSP MSP-3 formulation can be considered safer than other vaccine candidates tested so far." (specification, p. 44). Example 12 of the specification teaches Natural passive transfer of antibodies from mother to newborns (pp. 45-46). Example 13 of the specification teaches Studies in cerebral malaria patients (p. 46). Example 14 sets forth In vivo passive transfer experiments in *P. falciparum* infected SCID mice (pp. 47-48). However, none of these examples in the specification sets forth enablement for the claimed vaccine against malaria comprising MSP-3b or MSP-3c or MSP-3d or combinations of these peptides. The specification is not enabled for a vaccine; the examples, as described above, do not set forth in active immunization of an animal or human using the claimed vaccine, followed by a challenge.

The state of the art indicates that at present there are no vaccines that protect against malaria. Arevalo-Herrera et al indicates that because of the complexity of the parasite's life cycle the development of a universal, effective and long lasting vaccine is difficult (p. 444). Arevalo-Herrera et al states that since the use of whole malaria parasites as vaccines is not feasible, parasite sub-unit vaccines are being envisaged either making use of recombinant technology, peptide synthesis or naked DNA injection. Even though it is accepted that malaria vaccines need to simultaneously target the different parasite developmental stages, most vaccine trials concentrate on individual parasite targets, especially from *P. falciparum*. The of a multi-stage and multi-species vaccine is expected to be advantageous because of simultaneous priming of synergistic immune mechanisms targeting the main parasite species circulating in a given region. (p. 444, col. 2) Arevalo-Herrera et al indicates that even though most efforts towards vaccine development have been focused on *P. falciparum*, development of a worldwide efficient malaria vaccine will require the inclusion of components from two prevalent malaria species, *P. falciparum* and *P. vivax* at least (p. 444, col. 2). Bouharoun-Tayoun et al 2004 states that the study of parasite antigens targeted by ADCI effector antibodies has led to the characterization of MSP-3, a 48 kDa protein present on the surface of the *P. falciparum* merozoite. Cytophilic antibody response against

MSP-3 is highly correlated with protective immunity. MSP-3 is currently used as a candidate malaria vaccine in clinical trials (p. 2, col. 1). The art indicates that it is a vaccine candidate but to date no vaccine against malaria using MSP-3, the whole protein or portions of the protein, has been disclosed.

Further, the art teaches problems with other proteins from Plasmodium as vaccine components. Kurtis et al 2001 states that a vaccine is urgently needed to stem the global resurgence of *P. falciparum* malaria; LSA-1 is one of a few proteins known to be expressed by liver-stage parasites, holds particular promise as a vaccine (abstract). Kurtis et al 2001 states that despite "important advances, such as the circumsporozoite protein (CSP)-based vaccine called RTS,S, the goal of a safe and broadly effective malaria vaccine remains unfulfilled. The parasite's complex life-cycle offers several targets for intervention in the human host and the mosquito vector and vaccines against sporozoite, intrahepatic, blood and sexual stages of the parasite are currently in development." (p. 219, col. 1). As of 2001, there is no effective vaccine that comprises the LSA either alone or in combination with other malaria proteins. Further, because LSA is a liver specific antigen, investigation of its immunological significance is restricted to human studies because no homologue in mouse or non-human primate malarias has been identified (p. 219, col. 1). Others such as Taylor-Robinson et al 2001 have also indicated that LSA-1 may be a good candidate for a vaccine, but no vaccine has been produced that has been shown to be effective (see also Moorthy et al 2004; Ballou et al 2004; Joshi et al 2000; Kurtis et al 1999; Cox 1992; Ntumngia et al 2004; Stowers et al 2001). Shi et al, 1999 indicate that a multicomponent, multistage malaria vaccine can induce immune responses that inhibit parasite development at multiple stages. The rationale and approach used in the development of a multicomponent *P. falciparum* vaccine will be useful in the development of a multispecies human malaria vaccine and vaccines against other infectious diseases (see abstract). "Although studies of immunogenicity and the results of *in vitro* protection experiments have been promising for many of the single stage-specific vaccine candidate antigens, the test of *in vivo* protection has not always been satisfactory. There is consensus, however, that a highly effective malaria vaccine would require a combination of key antigens and/or epitopes from different stages of the life cycle and that induction of both humoral and cellular immunity is required for optimal efficacy. Such a multicomponent malaria vaccine would also circumvent the problems associated with host genetic restriction and antigenic variability in the case of single antigen-based vaccines." (Shi et al, 1999, p. 1615, paragraph bridging cols. 1-2). Shi et al 1999 also indicates that multiple protective immune responses against multiple antigens from different stages will

be needed to protect against malaria (p. 1618, col. 2). "Although a single-antigen and/or stage-specific vaccine could provide protection against infections, there are several reasons to advocate a multivalent, multistage malaria vaccine. A major concern with a single antigen-based vaccine is that an antigenic variant population of the parasite not recognized by the vaccine will cause infection (with heterologous parasites) and cause disease." (see p. 1618-1619).

In view of the fact that the specification does not set forth any enablement with regard to direction or guidance and the absence of working examples for the claimed vaccine composition, and the fact that the state of the art teaches that there are no single antigen (MSP-3b peptide or MSP-3c peptide or MSP-3d peptide or combinations of these peptide) or stage specific vaccines against malaria and the unpredictability and difficulty in obtaining an effective vaccine directed against malaria comprising the claimed peptides there would be undue experimentation necessary for a person of skill in the art to practice the claimed invention.

The rejection is maintained for the reasons of record. Applicant's arguments filed January5, 2005 have been fully considered but they are not persuasive. Applicant has asserted that the only conclusion that can be drawn from the cited references is that they are not relevant to the subject matter of the claimed invention. However, it is noted that the references were cited to give a review/information on the state of the art with regard to vaccines against malaria and the difficulty in developing a vaccine against malaria. The claims generically recite "vaccine against malaria"; none of the claims recite any specific Plasmodium species that causes malaria. Both *P. falciparum* and *P. vivax* are parasites that cause malaria in humans. Applicant has asserted that the Examiner is misinterpreting the claims to recite a commercialized vaccine and that the claims solely recite a vaccine. Applicant asserts that the sole criteria of a vaccine is to stimulate an immune response that can prevent an infection or create resistance to an infection or to reduce the parasite load or reduce or eliminate parasite replication or growth after invasion and that T-cell and antibody responses are indicative of an immune response. With regard to applicant's arguments, it is noted that the claims are interpreted as broadly as possible. The claims do not specify any particular characteristics or properties for the vaccine, only that it is a vaccine against malaria. Further, it is noted that stimulation of an immune response does not equate to vaccine protection.

On page 14 of the response Applicant lists the results from the clinical trials; however none of these are clearly indicative that the claimed peptides either alone

or in combination will protect against malaria. An immune response is not protection against infection. Applicant cited Singh et al (Annex II) and Meraldi et al (Annex III) to clearly demonstrate the success of the presently claimed invention in human studies. However, it is not clear that the peptides were tested individually claimed to protect against malaria. The rejection is maintained for the reasons of record.

The rejection is maintained for the reasons of record. Applicant's arguments filed June 27, 2005 have been fully considered but they are not persuasive. Applicant has asserted that the references cited by the Examiner, specifically Arevelo-Herrera et al and Shi et al, discuss multi-stage and multi-component vaccines, not the claimed vaccine (MSP-3 peptides). Applicant has provided Document I as reflecting the state of the vaccine art and demonstrates that non-Multistage vaccines are currently in clinical trials. However, the references cited in the 112, 1st paragraph rejection were cited to show that even after the filing date of the instant application, the development of a vaccine against malaria using any antigen has not been achieved. The state of the art at the time of filing is what is considered with regard to enablement.

The amount of direction or guidance presented in the specification and the absence of working examples is a hindrance to practicing the claimed invention. Applicants have not provided guidance in the specification toward the use of a vaccine against malaria. One skilled in the art would not accept on its face in view of the lack of examples given in the specification as being representative of the successful vaccine against malaria in view of the lack of guidance in the specification and the known unpredictability associated with malaria vaccines. The specification as filed fails to provide particular guidance which resolves the

known unpredictability in the art associated with vaccines against malaria. Since the specification fails to provide particular guidance for the successful use of a vaccine against malaria and the art teaches that this is not yet possible (i.e. highly unpredictable), it would require undue experimentation to practice the invention as presently claimed.

It is noted that the specification describes the steps of the claimed method to one skilled in the art, but does not provide any evidence that any of the claimed methods would function *in vivo* or *in vitro*. The issue of correlation is related to the issue of the presence or absence of working examples. Correlation as used herein refers to the relationship between *in vitro* or *in vivo* animal model assays and disclosed or a claimed method of use. An *in vitro* or *in vivo* animal model example in the specification, in effect, constitutes a working example, if that example correlates with a disclosed or claimed method invention. If there is no correlation, then the examples do not constitute working examples. (see MPEP 2164.02) The pending specification does not set forth such correlations for a working example of the claimed *in vivo* method.

Further, the specification would have been enabling as of the filing date involves consideration of the nature of the invention, the state of the prior art and the level of skill in the art. The state of the art is what one skilled in the art would have known, at the time the application was filed, about the subject matter to which the claimed invention pertains. The relative skill of those in the art refers to the skill of those in the art in relation to the subject matter to which the claimed invention pertains at the time the application was filed. The specification must be enabling as of the filing date, not evidence provided several years after the date of filing. The state of the art for a given technology is not static in time. It is entirely

possible that a disclosure filed on January 2, 1990, would not have been enabled. However, if the same disclosure had been filed on January 2, 1996, it might have enabled the claims. Therefore, the state of the prior art must be evaluated for each application based on its filing date. (see MPEP 2164.05(a)) In view of all of the above, the pending specification does not enable the claimed invention of a vaccine against malaria.

Applicant has asserted that the Examiner has not considered the evidence of Examples 10-11, which demonstrates ADCI provides a means of generating cross-strain protection since macrophages activated by antibodies to one variant can kill parasites in RBC of other strains and variants of *P. falciparum*. However, these examples do not show enablement for the claimed invention of a vaccine against malaria. It is noted that Applicant has not specifically defined the term vaccine. Absent any specific definition for vaccine, the Examiner has used the normally accepted definition for a vaccine, that being protection or prevention.

The Druilhe Declaration under 37 CFR 1.132 filed June 27, 2005 is insufficient to overcome the rejection of claims 4, 9, 25-27 and 29 based upon 112, 1st paragraph lack of enablement as set forth in the last Office Action. Applicant has asserted that the specification clearly demonstrate that the MSP-3 long synthetic peptides of the present invention are able to elicit antibodies in humans when administered in low doses with alum or Montanide that are able to kill the *P. falciparum* parasite or inhibit the growth of the parasite. The Examiner agrees with this statement, however this does not set forth any enablement for a vaccine against malaria. Please note that the claims directed to an immunogenic composition are not rejected under 112, 1st paragraph lack of enablement.

With regard to paragraph [2] of the declaration, there is no problem with how to obtain or make the claimed vaccine, but a problem with how to use the vaccine (i.e. provides protection against malaria or prevents malaria). With regard to paragraphs [3]-[9] it is noted that the specification does set forth evidence that the composition has immunogenic properties and that it is safe for immunization. However, again, this is not evidence of protection against malaria. The declaration also discussed passive transfer of antibodies, however, the claimed invention is directed to a vaccine against malaria comprising MSP-3c or MSP-3d, for example, and a pharmaceutically acceptable carrier. The claimed vaccine is used in active immunization, not passive immunization using antibodies. Paragraph [10] of the declaration states that the association of MSP-3 antibodies with protection against malaria was demonstrated in Dielmo with over 2 years of follow-up. Again, the claims are not directed to MSP-3 antibodies. Further, what protocols or procedures were followed to obtain the Dielmo data? Were the procedures set forth in the specification used? With regard to paragraphs [11]-[12], a drop in the level of parasitemia is not an indication of vaccine protection, it does show that malaria symptoms were reduced. The data also shows that both the antigen, MSP-3 and the antibodies were immunogenic. With regard to paragraph [14] Applicant has asserted that it is well known by scientists in this field that the goal of erythrocytic malaria vaccines is either to reduce the parasite load by preventing invasion of red cells or to prevent parasite replication and/or growth after invasion of the parasite. In this regard the present invention provides a mechanism to block the *P. falciparum* parasite as demonstrated in the specification. However, this definition is not what Applicant has set forth in the instant specification. Absent this definition or any specific definition for a vaccine,

the Examiner uses the currently accepted dictionary definition for a vaccine, which is protection or prevention of malaria. If the Examiner has missed applicant's definition for a vaccine against malaria stated in the instant specification, please direct the Examiner to the page and paragraph, where such support and definition has been made.

4. Claims 3-7 and 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Oeuvray et al 1994 (Blood, 1994, 84/5:1594-1602) or Oeuvray et al 1994 (Mem. Inst. Oswaldo Cruz, Rio de Janeiro, 1994, 89/Suppl. II:77-80).

Oeuvray et al 1994, for example, discloses the peptides, MSP-3a, MSP-3b and MSP-3c and a pharmaceutically acceptable carrier (abstract; materials and methods). The prior art discloses the specific amino acid sequences as set forth in SEQ ID NO: 11, SEQ ID NO: 12 and SEQ ID NO: 13 (p. 1595, col. 1). The prior art anticipates the claimed invention.

It is noted that the recitation of "vaccine" in claim 4, for example, is viewed as intended use. The recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Since the Patent Office does not have the facilities for examining and comparing applicants' compositions with the compositions of the prior art reference, the burden is upon applicants to show a distinction between the material

structural and functional characteristics of the claimed compositions and the compositions of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

The rejection is maintained for the reasons of record. Applicant's arguments filed January 5, 2005 have been fully considered but they are not persuasive. Applicant has asserted that neither of the references disclose SEQ ID NO: 11 to 14, and that only SEQ ID NO: 12 is disclosed. However Oeuvary et al (Blood, 1994) discloses SEQ ID NO: 11-13. Applicant has asserted that the MSP-3a and MSP-3c sequences are not the same as those presently claimed because there is a one amino acid difference. It would appear that they are the same or an obvious variant of the peptide. The function of the peptide is not altered since the prior art peptides are immunogenic. Applicant has asserted that neither reference discloses the MSP-3d, which is SEQ ID NO: 14. However, the claims indicate that the composition comprises one peptide (i.e. MSP-3c or MSP-3d) *or* a combination of said peptides. Therefore the prior art discloses the claimed invention.

With regard to Applicant's assertion that the art does not disclose an immunogenic composition or vaccine, it is noted that the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

5. Claims 3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oeuvray et al 1994 (Blood, 1994, 84/5:1594-1602) or Oeuvray et al 1994 (Mem. Inst. Oswaldo Cruz, Rio de Janeiro, 1994, 89/Suppl. II:77-80) taken with Saul et al 1999 (Vaccine, 1999, 17:3145-3159).

Oeuvray et al 1994, for example, teaches the peptides, MSP-3a, MSP-3b and MSP-3c and a pharmaceutically acceptable carrier (abstract; materials and methods). The prior art teaches the specific amino acid sequences as set forth in SEQ ID NO: 11, SEQ ID NO: 12 and SEQ ID NO: 13 (p. 1595, col. 1). The prior art teaches the claimed invention except for the composition comprising alum and/or Montanide.

However, Saul et al teaches malaria a composition comprising a *Plasmodium falciparum* protein formulated in Montanide (abstract; materials and methods). The *Plasmodium falciparum* protein used in the composition was a merozoite surface protein, MSP-1 and MSP-2, similar to the MSP-3. Mice were injected i.m. and s.c. (p. 3148, col. 1) and humans were immunized with 4 micrograms of antigen (p. 3148). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the components as set forth in either Oeuvray et al and Saul et al 1999 for the preparation of an immunogenic composition comprising peptides of the MSP-3 protein and Montanide as the adjuvant. Both references discuss the need for compositions to treat malaria, which is how the claimed composition would be used. The prior art of Oeuvray et al (either reference) taken with Saul et al 1999 teach the claimed invention, absent any convincing evidence to the contrary.

6. With regard to the prior art rejections set forth in paragraphs #4 and 5 above, Applicant's arguments filed June 27, 2005 have been previously addressed. It is noted that claim 4 should also be included in the 103 rejection set forth in paragraph # 5.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
March 15, 2005